

Clinical Edit Criteria Proposal

Drug/Drug Class: **Zovirax Cream® (acyclovir) Clinical Edit**

Prepared for: **Missouri Medicaid**

Prepared by: **Heritage Information Systems, Inc.**

☒ **New Criteria**

☐ **Revision of Existing Criteria**

Executive Summary

Purpose: Requires evidence of a FDA-approved indication for use.

Why was this Issue Selected: Zovirax Cream is a new dosage form of acyclovir that is indicated for genital herpes or herpes labialis. The product is for topical use, administered 5 times per day for up to 5 days. The product may be refilled once if sore persist.

Program-specific information:	Drug	How Supplied	AWP
	• Zovirax Cream® (acyclovir)	5% 2gm	\$35.28
		5% 5gm	82.03

Setting & Population: Patients with genital or oral herpes.

Type of Criteria:

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

Data Sources:

<input checked="" type="checkbox"/> Only administrative databases	<input type="checkbox"/> Databases + Prescriber-supplied
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Purpose of Clinical Edit Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Clinical Edit criteria, which is different from prior authorization or prior approval programs, assist in the achievement of qualitative and economic goals related to health care resource utilization without placing the entire utilization of a drug in a PA status. Screening the use of certain medications on the basis of clinical appropriateness can reduce costs by requiring evidence of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Clinical Edit criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Setting & Population

- Drug class for review: Zovirax Cream® (acyclovir)
- Diagnosis: History of genital or oral herpes

Approval Criteria

- Total days supply does not exceed 10 days in the past 30 days, or total quantity dispensed does not exceed 10gm in the past 30 days.
- Evidence of Acyclovir Ointment in patient's paid claims history in the past 12 months.
- The patient is diagnosed with one of the following medical conditions:

Approval Diagnoses

Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Historical Date Range	Client Approval (Initials)
Genital Herpes	054.1	NA	2 yr	
Herpes labialis	054.9	NA	2 yr	

Denial Criteria

- Prescription claim exceeds 10 days of therapy.
- Total days supply exceeds 10 days in the past 30 days.
- Total quantity dispensed exceeds 10gm in the past 30 days.
- Lack of Acyclovir Ointment claims in past 12 months.
- Lack of appropriate diagnosis.



Required Documentation

Laboratory results: ☐
MedWatch form: ☐

Progress notes: ☐
Other: ☐

Disposition of Edit

- **Denial:** Edit 682 “Clinical Edit”

References

1. USPDI, Micromedex, 2003.
2. Facts and Comparisons, 2003.

